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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,099	08/23/2001	Rajiv Indravadan Modi	CAPH 8016US	2239

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,099	MODI ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18,22,23 and 25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18,22,23 and 25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-15, 18, 22, 23, 33-35, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific microorganisms listed in claim 3 and the specific anti-infective agents listed in claim 2, does not reasonably provide enablement for any and all anti-infective agents "capable of causing adverse effects caused by destruction of commensals" and any and all microorganisms susceptible to the anti-infective agent or useful in the prevention or minimizing the adverse effects of the anti-infective agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant's specification provides enablement for the specifically claimed anti-infective agents (see claims 2) and microorganisms (see claim 3). Applicant's specification does not provide support to claim any and all anti-infective agents and any and all microorganisms "susceptible" to the anti-infective agents. The word susceptible is very broad in meaning. One would not necessarily know which microorganisms are susceptible to the anti-infective agent. One can be susceptible to a cold, but that does not mean that one will get a cold. Applicants have shown that list of specific antibiotics work with a specific set of microorganisms. For applicant to claim such broad lists of these is simply without merit since one of ordinary skill in the art would not be able to identify all of the species in these genera. Knowing only these specific microorganisms and these specific antibiotics would at best produce a short list of possible combinations, but how can applicant expect one of ordinary skill in the art to figure out each and every microorganism that might be susceptible to the broad list of anti-infective agents. Furthermore, just about every microorganism would be susceptible to an anti-infective agent since the term "susceptible" is broad to begin with.

Also, it is important to note that the field of biotechnology is so unpredictable that one would not necessarily know if any and all microorganisms susceptible to the anti-infective would work in the present invention. Microorganisms are living beings and are therefore, by definition unpredictable and cannot be relied upon to necessarily work with antibiotics to yield applicants results as disclosed in the instant specification.

There is no support for anti-infective agents "capable of causing adverse effects caused by destruction of commensals". Where in the specification is such support found ? These claims are simply too broad.

The examiner is not questioning whether the specific microorganisms of claim 3, 25, 36, 40 will work on the invention. The examiner is stating that one of ordinary skill in the art only given these specific microorganisms would be able to access what other microorganisms will work in the prevent invention. These claims (3, 25, 36, 40) are not in question in this rejection, but what is in question is would one of ordinary skill in the art know which of the any and all microorganisms useful in preventing or minimizing adverse effects of the anti-infective agent would actually work in this invention. With the anti-infective agents also being broadly claimed this makes the task of figuring out which microorganism could work in this invention even more unpredictable. Since microorganisms are living beings and not apparatus, they are very unpredictable and it is not easy to predict which microorganisms will perform as the invention requires. Specific microorganisms are susceptible to specific anti-infective agents and not all of them. To test any and all anti-infective agents to see if they would work in the invention along with the right microorganism is simply beyond the means of the patent office. The patent office does not have the facilities nor the time to test to see if any and all microorganisms would work in this invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 18, 22, 23, 25-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record and for the reasons which follow.

What is an anti-infective agent "capable of causing adverse effects caused by destruction of commensals" or microorganisms "useful in the prevention or minimizing the adverse effects of the anti-infective agent". These are terms which really have no art recognized meanings. Unless applicant puts in the specific types of microorganisms and anti-infective agents used as shown in the instant specification, these claims as they are written are not understood.

How does destroying commensals cause adverse effects ? Adverse effects of what ? What adverse effects of the anti-infective agent ? How would one of ordinary skill in the art really know which microorganisms and anti-infective agents applicant is referring to ? It is simply not clear what microorganisms and antiinfective agents applicant is envisioning other than the specifically claimed ones as noted above. If applicant deletes this language and inserts the specific microorganisms and anti-infective agents noted above the rejection will be dropped.

Claim Rejections - 35 USC § 102

Claims 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 5247 (FR).

FR is of record. It teaches using tetracycline which is a known antibiotic. Such an antibiotic would perform the claimed characteristics.

FR **does** teach that a barrier between the antibiotic (the anti-infective agent) and the bacilli (the microorganism) is used, meaning that FR indeed does keep the microorganism and the anti-infective agent away from each other. Thus, the claims are anticipated by the reference.

Claim Rejections - 35 USC § 103

Claims 1-15, 18, 22, 23, 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 5247 in view of FR 6855 and further in view of Black et al.

Applicant argues essentially the same as above. Black was cited to show that ampicillin is also well known to be used for the same purpose as in the disclosed invention. One of ordinary skill in the art would have been motivated to use ampicillin

instead of tetracycline since Black yielded such beneficial results and since ampicillin is also a well known antibiotic like tetracycline.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Black was used as part of the 35 USC 103 rejection and was not used under 35 USC 102 as argued by applicant. Applicant cannot expect Black to contain all of applicant's invention. It was used as a secondary reference which is clear from the record.

It is clear from Black that it was known that ampicillin was known to be combined with the claimed microorganisms for the known purpose at the time the invention was made. FR 5247 makes it clear that to separate the ingredients (anti-infective agent and the microorganism) and put a barrier between them would have been well known to one of ordinary skill in the art. Thus, to put ampicillin and the claimed microorganism together in the same tablet would have been obvious since it was well known to provide a barrier between the two ingredients and to administer them at the same time in the same tablet as taught by the French references and since ampicillin which is also a well known antibiotic like tetracycline is used and yields beneficial results. The fact that the French references do not mention ampicillin does not take away from the fact that ampicillin and tetracycline are both well known antibiotics. Applicant even admits that

they were both known by the 1960's. Thus it was merely the choice of the skilled artisan to use either ampicillin or tetracycline in an effort to optimize the desired results. FR 5247 does indeed provide clear motivation to use the protective barrier. Why else would FR 5247 bother to add one ? Applicant argues that Black gives his microorganism and anti-infective agent at different times but Black is not the primary reference. Black was cited merely to show that ampicillin can be used instead of tetracycline since it is also a well known antibiotic that yields beneficial results when used.

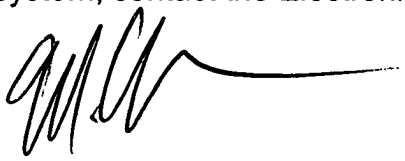
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller
Primary Examiner
Art Unit 1654

MVM